

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee : Harris *et al.*
Serial No. : 10/717,217
Filed : November 18, 2003

Art Unit : 1614
Examiner : Raymond J. Henley III
Confirm. No.: 6038

Patent No.: 7,504,376

Issued : March 17, 2009

Title : **METHODS AND COMPOSITIONS FOR INCREASING THE
ANAEROBIC WORKING CAPACITY IN TISSUES**

MAIL STOP OFFICE OF PETITIONS / OPLA

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

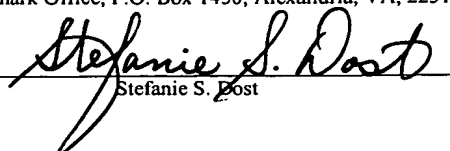
**PETITION PURSUANT TO 37 CFR § 1.181(a)(3) REQUESTING
RECONSIDERATION OF THE DISMISSAL OF THE PETITION FOR
RECONSIDERATION OF PATENT TERM ADJUSTMENT PURSUANT TO
37 CFR § 1.705(D) IN VIEW OF WYETH v. KAPPOS**

Dear Sir:

Patentee hereby petitions pursuant to 37 CFR § 1.181(A)(3) for reconsideration of the dismissal of the Petition, filed May 15, 2009, requesting reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent at time of issuance. In view of the recent decision issued by the United States Court of Appeal for the Federal Circuit, in Wyeth and Elan Pharma Int'l Limited v. Kappos No. 2009-1120 (Fed. Cir. 2010), which affirmed the decision reached in United States District Court for the District of Columbia in Wyeth v. Dudas, No. 07-1492, 88 U.S.P.Q.2d 1538 (D.D.C. 2008), holding that the USPTO had misconstrued 35 U.S.C. § 154(b)(2)(A), reconsideration of the Patent Term Adjustment days to increase the total PTA by 525 days from 493 days to 1,018 days respectfully is requested. The Decision dismissing the Petition was mailed December 22, 2009. Thus, this Petition is filed within two months of the decision of the Office of Petitions. Any fees that may be due in connection with the filing of this paper should be charged to Deposit Account No. 02-1818.

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Date of Deposit: **January 25, 2010**

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop Petitions, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

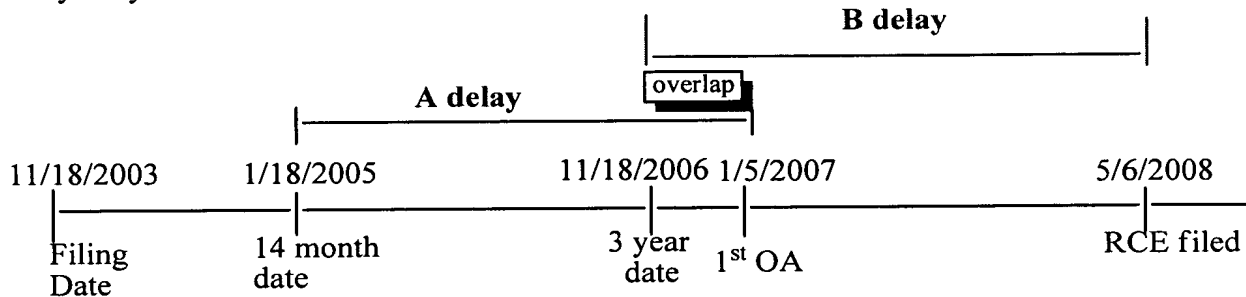

Stefanie S. Post

Basis for the Petition of May 15, 2009

Upon issuance of the present patent, the Patent Term Adjustment History and calculations were updated to include an entry on 02-25-2009 that recites "PTA 36 Months" with a zero total for PTO Delay Days and only 493 PTO delay days were accorded this patent at allowance.

Calculation of Patent Term Adjustment Days

The following timeline is provided, showing the pertinent dates and "A delay" and "B delay" days:



The instant application was filed November 18, 2003. The first Office Action for the instant application was mailed by the Office on January 05, 2007. This is a **PTO delay of 717 days** beyond the 14-month due date. Accordingly, Patentee had accumulated 717 PTO delay days under 35 U.S.C. §154(b)(1)(A) by January 05, 2007, or **717 "A days."**

35 U.S.C. §154(b)(1)(B) establishes that a patent's term is to be extended for each day that the application is pending beyond three years from the filing date. The three-year clock stops if certain events occur, such as the filing of a *Request for Continued Examination* (RCE). **The PTA 36 month deadline for this application was November 18, 2006** (48 days before receipt of a first Office Action). In the instant application, the filing of a *Request for Continued Examination* on May 06, 2008, stopped the three-year clock in the same manner as an issuance. Accordingly, Patentee had accumulated an additional **534 PTO delay days** under 35 U.S.C. §154(b)(1)(B), or **534 "B days."**

35 U.S.C. §154 states that, to the extent that days accorded under 35 U.S.C. §154(b)(1)(A) and §154(b)(1)(B) overlap, that patent term adjustment "shall not exceed the actual number of days the issuance of the patent was delayed." Patentee respectfully submits that there is a **48 day** overlap between the days accorded under §154(b)(1)(A) and §154(b)(1)(B) because the first Office Action was received 48 days after the three year time period prescribed in §154(b)(1)(B). Therefore, there are **48 overlapping A/B days.**

Accordingly, Patentee is entitled to 717 PTO delay days under 35 U.S.C. §154(b)(1)(A) **and** 534 PTO delay days under 35 U.S.C. §154(b)(1)(B) minus the overlapping 48 A/B days for a total of 1,203 PTO delay days, less the 185 APPL delay days for a PTA for this patent of **1,018 days**.

On May 15, 2009, in view of the holding in Wyeth v. Dudas (D.D.C., 2008), Patentee timely filed a Petition indicating that the 493 PTO delay days accorded this patent at allowance was incorrect and respectfully requested reconsideration of the calculation of the Patent Term Adjustment days to increase the total PTA by 525 days from 493 days to 1,018 days. The increase of the PTA are days under 35 U.S.C. 154(b)(1)(B), which the Office stated overlaps with the days accrued under 35 U.S.C. 154(b)(1)(A). The Court in Wyeth v. Dudas, holding that the Office's construction of 35 U.S.C. § 154(b)(2)(A) was incorrect, stated that "[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day." According to the Court, "[t]he problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the period before it has been delayed" (original emphasis). In this instance, 486 "B days" did not occur on the same day as any "A days" and thus did not overlap. On this basis, Patentee petitioned for recalculation on PTA in accord with the holding in Wyeth v. Dudas, requesting that days under both 35 U.S.C. 154(b)(1)(A) and 35 U.S.C. 154(b)(1)(B) that do not overlap be counted.

Dismissal of the Petition

On December 22, 2009, the Office of Petitions mailed their decision dismissing the Petition, stating that the 534 days of patent adjustment under 37 CFR 1.702(b) overlap with the 717 days of patent term adjustment under 37 CFR 1.702(a)(1). The rationale for dismissing the Petition is that the Patentee's interpretation of the period of overlap, which was consistent with the holding in Wyeth, was found to be inconsistent with the Office's interpretation of the overlap provision. The dismissal states that:

the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv) or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 35 U.S.C. 154(b)(1)(B). . . . The Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

...
The 534 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 717 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 717 days and the 534 days is neither permitted nor warranted. 717 days is the actual number of days issuance of the patent was delayed. Considering the applicant delay of 185 days, the patent term adjustment at issuance is 493 (717-185) days.

Wyeth v. Kappos No. 2009-1120 (Fed. Cir. 2010)

On January 7, 2010, the Federal Circuit affirmed Wyeth v. Dudas (D.D.C., 2008), in which the district court found that the USPTO had misconstrued 35 U.S.C. § 154(b)(2)(A). As reviewed in Wyeth v. Kappos, the PTO's definition of 'period of delay' caused the B guarantee provision to start with the filing of the application instead of three years later. Using this interpretation, the PTO uses either the greater of the A delay or B delay to determine the appropriate adjustment of PTA, but never combines A delay and B delay.

The Federal Circuit affirmed the District Court's grant of summary judgment for Wyeth, stating:

This court detects no ambiguity in the terms "periods of delay" and "overlap" [of § 154(b)(2)(A)]. Each term has an evident meaning within the context of section 154(b). The limitation in section 154(b) only arises when "periods of delay" resulting from violations of the three guarantees "overlap." 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply.

The Federal Circuit further stated that:

"[t]he 'period of delay' for purposes of the A clause therefore runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action," and "[t]he 'period of delay' under the express language of the B clause therefore runs from the three-year mark after filing until the application issues."

With respect to the Office's interpretation of the statute, the Federal Circuit opined that:

Reading this framework into section 154(b)'s limitation provision makes it clear that no "overlap" happens unless the violations occur at the same time. Each "period of delay" has its own discrete time span whose boundaries are defined in section 154(b)(1). That is, each has a start and an end. Before the three-year mark, no "overlap" can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(B)(2).

Under the PTO's strained interpretation, B delay can occur anytime after the application is filed. To the contrary, the language of section 154(b) does not even permit B delay to start running until three years after the application is filed. The PTO's position cannot be reconciled with the language of the statute. Thus,

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Petition Pursuant to 37 CFR § 1.181(a)(3)

returning to the district court's decision, this time with affirming approval: "The problem with the PTO's interpretation is that it considers the application delayed under [the B guarantee] during the period before it has been delayed." (emphasis in the original)

The Federal Circuit in Wyeth v. Kappos concluded that:

Section 154(b)'s language is clear, unambiguous, and intolerant of the PTO's suggested interpretation. For that reason, this court accords no deference to the PTO's greater-of-A-or-B rubric.

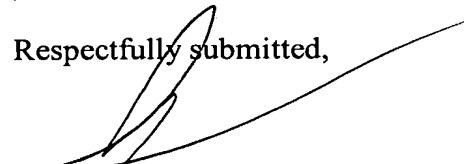
Patentee respectfully requests reconsideration of the dismissal of the Petition, in view of the holding stated in Wyeth v. Kappos (Fed. Cir. 2010). The rationale set forth in the dismissal of the petition has been found to be irreconcilable with the language of the statute. Accordingly, Patentee respectfully requests reconsideration and grant of the Petition for reconsideration of the Patent Term Adjustment and correction of the PTA days. Patentee respectfully requests that the calculation of the PTA days include days under 35 U.S.C. §154(b)(1)(A) and under 35 U.S.C. §154(b)(1)(B) that do not overlap. Thus, the Patentee respectfully submits that PTA for this patent should be:

PTO delay (717 "A days" plus 534 "B days" minus 48 "A/B overlap days") or 1,203 days minus APPL delay (185 days) = 1,018 days.

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Respectfully submitted,



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